# UNITED STATES PATENT AND TRADEMARK OFFICE

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/037,254 | 01/04/2002 | Jeffrey H. Burbank | T4342-14516US01 | 6185 |

181          7590          03/30/2011
MILES & STOCKBRIDGE PC
1751 PINNACLE DRIVE
SUITE 500
MCLEAN, VA 22102-3833

| EXAMINER |
|---|
| ARCHER, MARIE |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3769 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 03/30/2011 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocketing@milesstockbridge.com
sstiles@milesstockbridge.com

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<td colspan="2" align="center">Application No.</td>
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<td colspan="2" align="center">10/037,254</td>
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<td colspan="2">MARIE ARCHER</td>
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*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on <u>16 July 2010</u>.

2a) ☐ This action is **FINAL**.  2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) <u>1-6,9-13,19,20,25-27,32,33,42-51 and 53-61</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) <u>1-6,9-13,19,20,25-27,32,33,42-51 and 53-61</u> is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All  b)☐ Some * c)☐ None of:

        1.☐ Certified copies of the priority documents have been received.

        2.☐ Certified copies of the priority documents have been received in Application No. _____.

        3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Application number 10/037,254 has been transferred to Marie Archer. The

examiner acknowledges the response filed 07/16/2010. Claims 1-6, 9-13, 19-20, 25-27,

32-33, 42-51 and 53-61 are pending in the application.

### *Response to Arguments*

Applicant's arguments filed on 07/16/2010, with respect to the **35 USC 101**

**rejection** have been fully considered and are persuasive.  The rejection of claims 1-6,

9-13, 19-20, 25-27, 32-33, 42-51 and 54-61 has been withdrawn.

Applicant's arguments filed on 07/16/2010, with respect to the **35 USC 112 first**

**paragraph rejection** have been fully considered and are persuasive.  The rejection of

claims 1-6, 9-13, 19-20, 25-27, 32-33, 42-51 and 54-61 has been withdrawn.

Applicant's arguments filed on 07/16/2010, with respect to **the 35 USC 112**

**second paragraph rejections** have been fully considered <u>but they are not persuasive</u>.

While the applicant has set forth how one of ordinary skill in the art would interpret the

claim to require based on known methods, the examiner has not found anywhere in the

arguments on pages 13-14 of the reply filed on 07/16/2010 a reasoned statement for

the lack of indefiniteness of the rejected claims.  A more detailed rationale to set forth

the reasons why the claims are indefinite is provided in this office action.

Applicant's arguments filed on 07/16/2010, with respect to the **35 USC 102**

**rejection** have been fully considered and are persuasive.  Therefore, the rejection has

been withdrawn.  However, upon further consideration, a new ground(s) of rejection is

made in view of U. S. Patent 5,910,252 to Truitt.


### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine
grounded in public policy (a policy reflected in the statute) so as to prevent the
unjustified or improper timewise extension of the "right to exclude" granted by a patent
and to prevent possible harassment by multiple assignees.  A nonstatutory
obviousness-type double patenting rejection is appropriate where the conflicting claims
are not identical, but at least one examined application claim is not patentably distinct
from the reference claim(s) because the examined application claim is either anticipated
by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140
F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29
USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.
1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422
F.2d 438, 164 USPQ 619 (CCPA 1970); and  *In re Thorington*, 418 F.2d 528, 163
USPQ 644 (CCPA 1969).
  A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d)
may be used to overcome an actual or provisional rejection based on a nonstatutory
double patenting ground provided the conflicting application or patent either is shown to
be commonly owned with this application, or claims an invention made as a result of
activities undertaken within the scope of a joint research agreement.
  Effective January 1, 1994, a registered attorney or agent of record may sign a
terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with
37 CFR 3.73(b).


**Claims 9 and 12 are** rejected on the ground of nonstatutory obviousness-type

double patenting as being unpatentable over **claim 11 of U. S. Patent 7,040,142**

**Claims 9 and 12** of the instant application are directed to a leak detection device in a

blood circuit comprising two detectors capable of detecting blood leak conditions

associated with different phenomenon; the detectors including at least one of an air

detector and a fluid detector. The system further includes a signal combiner for

combining the acquired signals and producing a response. **Claim 11** of the conflicting

patent are directed to a device for detecting a leak from a blood circuit comprising at

least two detectors configured to detect infiltration of air into the circuit and blood

outside the circuit. The device is capable of generating a response based on the

detected signals.

The examiner has interpreted these claims are an obvious change in scope.

## Claim Rejections - 35 USC § 112

### Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly
> claiming the subject matter which the applicant regards as his invention.

**Claims 2-5, 9, 19, 20, 25-27, 42-48, 51 and 54-61** are rejected under 35

U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and

distinctly claim the subject matter which applicant regards as the invention.

**With respect to claims 2-5,** parent claim 1 recites a method step which includes

"deriving a composite signal responsive to said two leak detection signals". Dependent

claims 2-5 provide limitations to the "deriving" step by indicating that the deriving

includes "calculating a probability", wherein the calculating include applying the signals

to a network classifiers", the deriving further includes combining the two signals and

"applying a weight to the signals". When analyzing these method steps as a whole is

unclear how are they logically connected to produce a useful result. It appears that the

"deriving" step would produce at least two independent results: one produced by

applying the signals to a "network classifier" and another one produced by adding the

signals after applying a weight factor. It is unclear how are these results utilized to produced a single output.

**Claim 4** recites the limitation "said calculation" in line 1. There is insufficient antecedent basis for this limitation in the claim.

**Claim 9**, lines 3-6 recites: "a signal combiner connected to form a combination signal responsive" and "said signal combiner being such that both sensitivity and reliability of leak detection…."

First, the "signal combiner" has been interpreted as hardware, so that it can be connected. However, it is not clear what type of "connection" must be made so as to "form a combination signal." Second, the phraseology "being such" is indefinite since it is not clear what the element of the claim requires.

In general the claim is ambiguous and lacks any specific structural relationship between the elements, since all the limitations of the claim are directed to what appears to be functional language or intended use, it is unclear how these elements are connected so as to produce a useable device.

**Claim 19** recites: "A method of detecting an alarm condition in a medical treatment machine, comprising the steps of:

combining detector signals from at least two indicators of an alarm condition such that a prediction of an alarm state is generated thereby <u>and such that said prediction possesses at least one of a higher reliability and a higher sensitivity than said detectors signals uncombined</u>"

It is not clear what "higher" requires, there is no reference for comparison. In addition the above indicated clause appears <u>to be directed to limitations to the data</u> obtained by the method which, from the examiner's point of view, <u>does not limit the</u> <u>method steps</u>.

**Claim 25** recites: "said combining being effective to yield a prediction". It is unclear how a method step (combining) can be categorized as "being effective" or what is the measure of "effectiveness".

**Claim 27 recites**: "wherein said combining has the effect of amplifying a reliability of an estimate". It is unclear what this claim is intended to limit. The parent claim is directed to a method, the end effect of a method step does not provide any limitation.

**Claim 42**, lines 8-9 recites: "said signal filter being configured such that a prediction of a leakage of fluid from said medical treatment machine is generated by <u>combining said at least two."</u> It is unclear what the "at least two" elements are.

**Claims 45 and 46** recite: "wherein said signal filter includes a network classifier". "Signal filter" has been interpreted as hardware, since it requires to be "connected", as indicated in parent claim 42 and the term "network classifier" as software, it is unclear how these claims further limit the device element of the parent claim. The examiner does not consider machine readable instructions stored in a device as limiting any aspect of the device's structure or functionality.

**Claim 51 recites**: "detecting first and second signals from first and second sensors, respectively, <u>the sensors detecting respective physical parameters associated</u>

with the blood circuit; and…". The claim preamble recites a method, the above indicated

clause appears to be directed to a functional or operational aspect of a device, and

therefore it is unclear whether the claim as a whole is directed to a method or to a

device.

**Claim 54** recites: "a signal filter adapted to combine detector signals from at least

two signals indicating an alarm condition to generate a weighted sum of the at least two

signals and indicating an alarm condition responsively to the weighted sum the

weighted sum has a more reliable indicator of the alarm condition than either of said

detectors signals alone;

The examiner has interpreted the above indicated clause as positively recited

method steps. The claim is directed to a device. See arguments with regard to claim 51.

Claims 20, 26, 43, 44, 47, 48 and 55-61 are rejected for depending on a rejected

base claim.

### *Fourth paragraph*

The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

A claim in dependent form shall contain a reference to a claim previously set forth and then specify a
further limitation of the subject matter claimed. A claim in dependent form shall be construed to
incorporate by reference all the limitations of the claim to which it refers as his invention.

**Claims 27, 32-33, 43, 53 and 56-59** are rejected under 35 U.S.C 112, fourth

paragraph as being an improper dependent claim for failing to further limit the subject

matter of the claim upon which it depends.

**With regard to claims 27, 32-33 and 43** the parent claim is directed to a method, these claims provide limitations to the machines used in the method, data or to an end effect or result of a method step rather than to the method steps per se.

**With regard to claim 43 and 56-59**, the parent claim is directed to a device. These claims provide limitations to the data ('predictions", "indicators" or "alarm conditions") used or generated by the device rather than to the device's elements.


*Note to Applicant Regarding Claim Interpretation (intended use)*

The words "for" and "configured to" in the claim(s) may be interpreted as intended use. Intended use/functional language does not require that the reference specifically teach the intended use of the element. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

With regard to **intended use in the claim preamble**, if the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. See MPEP 2111.02 (II).

## *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form

the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1, 3, 9-12 and 54-61** are rejected under 35 U.S.C. 102(b) as being

anticipated by U. S. Patent 5,910,252 to Truitt. Truitt teaches **an extracorporeal blood**

**treatment with a single apparatus** which is capable of a plurality of extracorporeal

blood treatments (col. 2, lines 50-52). An **object of the invention is to automatically**

**ascertain treatment conditions which place the patient at risk and to**

**automatically correct such conditions and/or notify the operator about such**

**conditions** during the extracorporeal treatment of blood.  Another object is to notify the

operator of conditions requiring operator assistance (col. 2, lines 57-63)

FIG. 1 is an illustration of an extracorporeal blood treatment apparatus incorporating the

present invention, attached to a patient undergoing extracorporeal blood treatment.

 FIG. 2 is a block diagram of the two parts of the extracorporeal blood treatment

apparatus shown in FIG. 1. FIGS. 3a and 3b are an expanded block diagram of the

components of a selection, control and monitoring system of the extracorporeal blood

treatment apparatus shown in FIG. 2. (col. 3, lines 35-40).  Figures 2 and 3b have been

annotated by the examiner to show the relevant system components as they relate to

the rationale provided below:

To select, control and monitor each of the treatment protocols, **the apparatus 30**

includes a protocol selection, **control and monitoring system 48** which is generally

shown in FIG. 2. **One of the components** 50 is a **first pressure sensor 51** connected

in the access line 34. The **first pressure sensor 51 allows the blood pressure of the**

**access line 34 to be monitored,** among other things. **A second pressure sensor 53**

is connected in the primary circuit 38 between the first pump 52 and an entrance to the

primary chamber 44. **One function of the second pressure sensor 53 is to detect**

**and monitor the pressure of the blood supplied to an entrance to the primary**

**chamber 44**. An <u>**alarm condition is indicated**</u>, for example, **if the blood pressure at**

**the entrance falls below a predetermined value**, <u>**in which case blood may be**</u>

<u>**leaking**</u>. **A third pressure sensor 54** is connected at the outlet of the primary chamber

44.
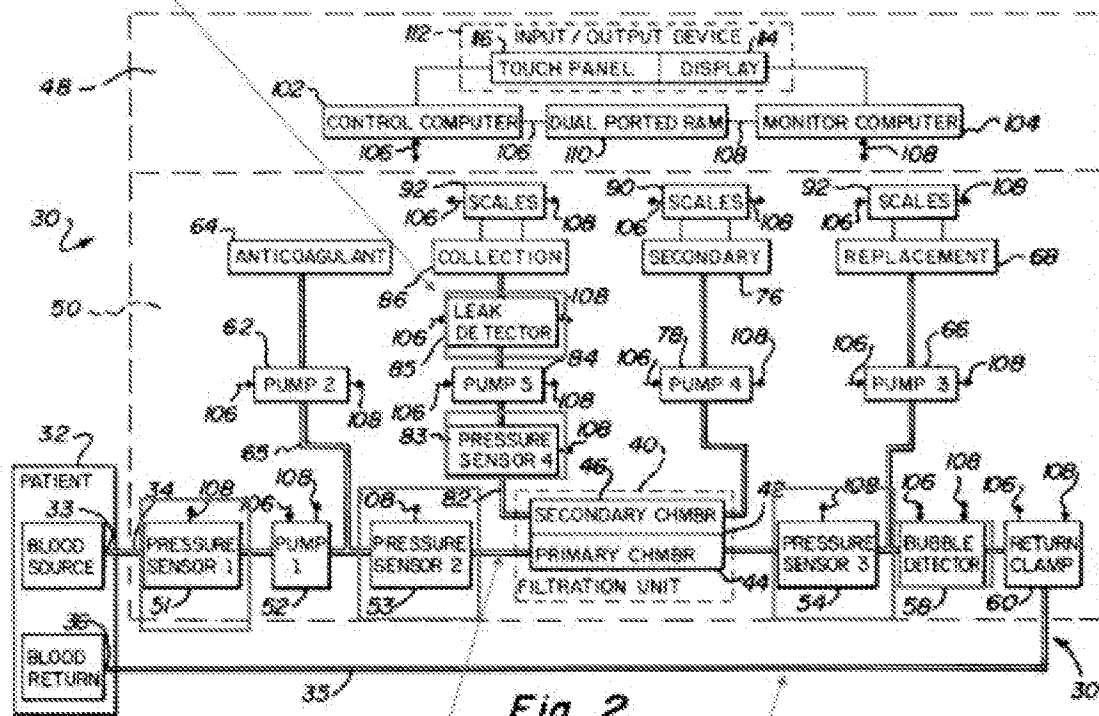
Fig. 2

One of functions **of the third pressure sensor 54 is to monitor the pressure of the**

**blood in the return line 35 at the exit from the primary chamber 44**.  By comparing

the pressures sensed by the sensors 53 and 54 at the entrance and exit of the primary

chamber 44, the integrity of the flow path through the primary chamber can be

monitored and, in particular, clotting of blood can be detected.  **In addition, if the**

**return pressure detected by the third pressure sensor 54 is below a desirable**

**level, <u>disconnection of the return line 35 or the return catheter 36 may be</u>**

**<u>indicated, which is treated as an alarm condition</u>**, as further described below (col. 4,

lines 25-55). The leak detector 85 is also located in the collection line 82.

The examiner has interpreted that the disconnection of a return line or return catheter will produce a blood leak by allowing blood to exit the circuit.

**The leak detector 85 is one of many known in the art and detects blood leaking into the secondary chamber by detecting blood in the collection fluid, typically by o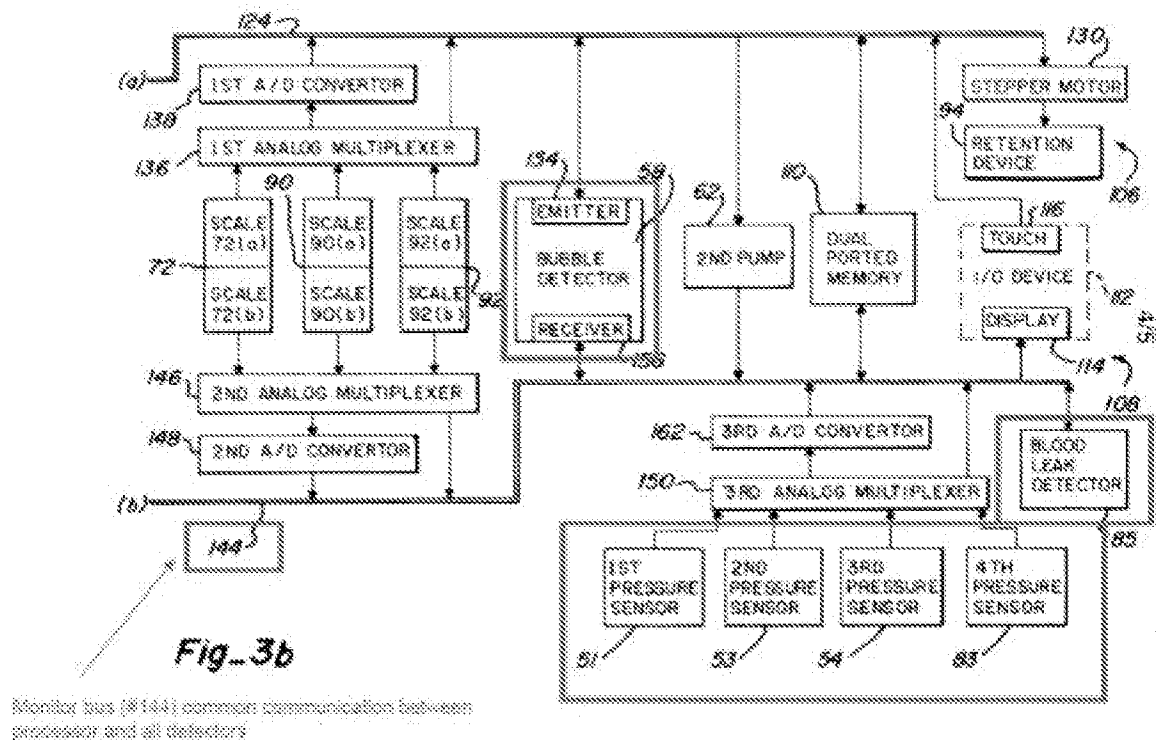ptical means** (col. 6, lines 12-16). **The selection, control and monitoring (SCM) system 48 of the apparatus 30 includes a control computer 102 and a monitor computer 104, as shown in FIG. 2.** The control and monitor computers 102 and 104 are connected in control and monitor signal paths 106 and 108, respectively, with each of the pumps 52, 62, 66, 78 and 84, each of the scales 72, 90 and 92, the bubble detector 58 and return clamp 60. **The pressure sensors 51, 53, 54, and 83 and the leak detector 85 are connected only to monitor signal path 108** (col. 6, lines 33-35 and 51-57). The monitor computer 104 includes a monitor processor 140 and a monitor memory 142 connected by a monitor bus 144 (col. 9, lines 23-25, figure 3b).

The monitor **processor 140 is in two-way communication with the leak detector 85** via signals sent over the monitor bus 144.  The leak detector 85, in cooperation with the monitor processor 140, conducts self-tests periodically to determine its operational integrity (col. 10, lines 65-67).

A **bubble detector 58** is connected in the primary circuit 38 downstream of the third pressure sensor 54.  The **bubble detector 58** is one of many known in the art and its function is **to detect the presence of bubbles and microbubbles in the treated blood being returned to the patient 32 in the return line 35** (col. 4, lines 58-64).

Fig_3b

The **monitor processor 140 and the control processor 122 are in two-way communication with the bubble detector** 58 via signals sent over **the monitor bus 144 and the control bus 124**, respectively (col. 11, lines 3-7, figure 3b).

**The signals from the pressure sensors 51, 53, 54 and 83 (figure 2) may be utilized by the monitor processor 140 to determine integrity of the primary and secondary circuits 38 and 74 (Figure 1), and the condition of the semi-permeable membrane 42, among other determinations** (col. 11, lines 24-30). Figure 1, annotated by the examiner shows character reference #38 and #74 as indicating the lines comprised between the input and output access points of the circuit, hence the examiner has

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interpreted that the monitor processor is configured to determine the integrity of the

complete extracorporeal circuit.



Figure 1 of U. S. Patent 5,910,252
annotated by the examiner

Fig-1
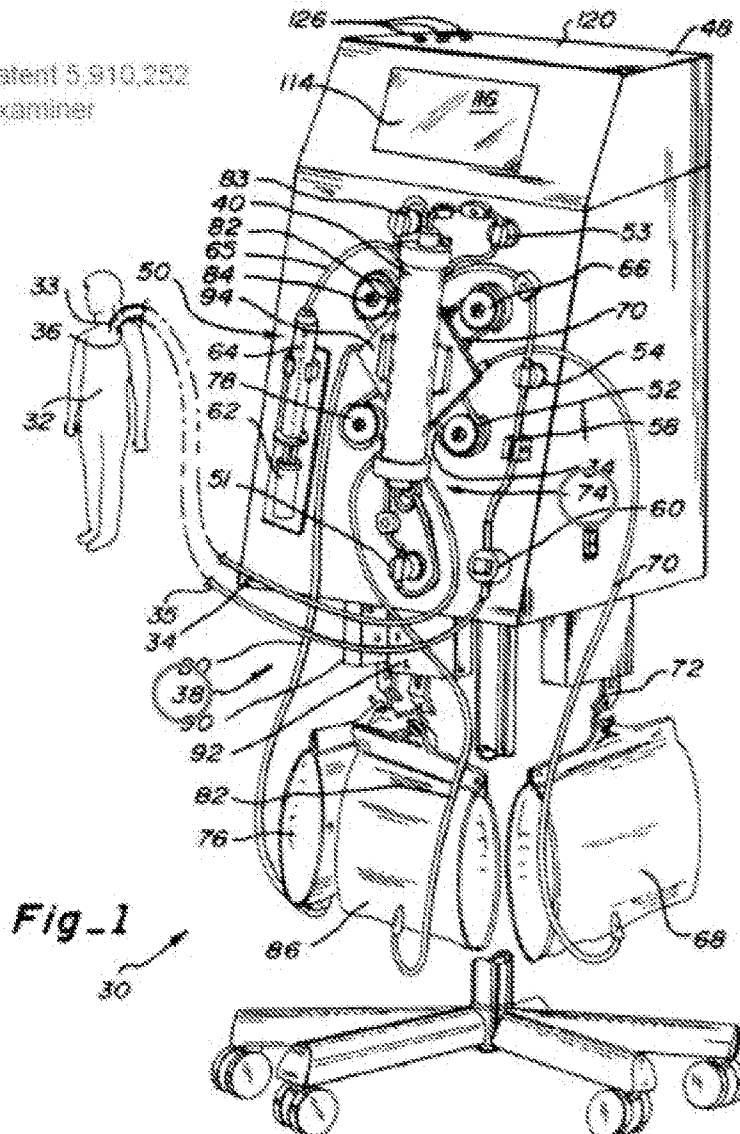
The determinations made by the monitor processor 140 are used to monitor the

status of the apparatus 30 and the status of the treatment being performed.

Based on these determinations, the monitor processor 140 reacts to perceived

**alarm conditions and notifies the operator about such alarm conditions by**

**emitting an alarm and displaying information about the alarm** (col. 10, lines 42-53).

**Signals read by the monitor processor 140 about the treatment being performed**

**including the rates of operation of each of the pumps 52, 62, 66, 78 and 84, the**

**rate of fluid dispensing and collection, the status of the return clamp 60, the**

**presence and volume of bubbles, the presence of blood leaks or of other**

**conditions detected jeopardizing the safety of the treatment and other**

**information are used to interpret alarm conditions** (col. 11,  lines 24-30).

   **With regard to claim 10**, Truitt's device is an IC based device, there is nothing

that would prohibit the incorporation of an analog summing circuit within the processor

or as an external packaged device.

   **With regard to claims 54 and 60**, the examiner has interpreted "signal filter" as

the processor in Truitt's device since the functional limitations provided are substantially

the same as the functional capabilities of Truitt's processor: combine signals. From the

examiner's point of view there is nothing that would prohibit the generation of a linear or

non-linear combination. In addition a processor can store or execute any type of

machine readable instructions or algorithms. "Network classifier" has been interpreted

by the examiner as an algorithm

   **With regard to claims 56-59,** see rejections under 35 USC 112 fourth

paragraph. The examiner has interpreted parent claim 54 as being directed to a device;

the above-mentioned claimed are directed to data such as "signals", "indicators" or

"predictions".  They have not been considered as limiting the scope of the claim.

The examiner has interpreted Truitt's teachings as follows: a system and a

method for monitoring extracorporeal treatment protocols are provided.  The system

includes at least six detectors as indicated in figures 1 and 2: four pressure sensors, a

leak detector and a bubble detector. Blood leakage is detected in at leas two different

manners with two independent detectors using different phenomenon. The first

independent manner is by means of sensing a change in pressure in at least two

different points in the circuit, as indicated in figure 1 with respect to the second and the

third pressure sensors (#53 and #54). The second independent manner is by means of

an optical leak detector (#85). In addition, the system is capable of detecting air in the

circuit through the bubble detector. Pressure differences and changes in the optical

characteristics of the fluid have been interpreted by the examiner as different

phenomenon. The system is computer based and includes two monitors (#'s 102 and

#104) which include respective processors (#122 and #140). The signals produced by

the plurality of sensors are used by the processor to generate alarm conditions which

are displayed to the user. The examiner has interpreted the processor as a signal

combiner since it has the capability to combine the various signals received from the

detectors in order to make a determination regarding the integrity of the circuit . The

determination results in an alarm condition which is displayed to the user. A

determination is made as to the extracorporeal system's integrity based on the signals

produced by the plurality of detectors in the circuit.

From the examiners point of view, there is nothing in Truitt's system and method

that would prohibit generating a high sensitivity and reliability detection or anything

indicating an ineffective determination about a leakage.


### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

**Claims 2, 4, 5,13 and 51** are rejected under 35 U.S.C. 103(a) as being

unpatentable over U. S. Patent 5,910,252 to Truitt as applied to claims 1, above in view

of U. S. Patent 6,609,036 to Bickford. Truitt was previously described but does not

teach the derivation of the composite signals by calculating a probability based on

applying a network classifier or applying weights to the respective signals prior to

adding them. Bickford teaches **a system and method for process parameter**

**estimation using operating mode partitioning and, in particular, to a system and**

**method for performing high sensitivity surveillance of an asset such as a process**

**and/or apparatus preferably having at least two distinct modes of operation**

**wherein surveillance** is performed using an operating mode partitioned parameter

estimation model of the asset (col. 1, lines 18-25). With reference to figure 2, **the**

**operating mode determination procedure 26  used to classify each observation**

**included in the training data set 24 may be, in general, performed using any**

**method suitable for determining the operating mode of the asset 12 given an**

**observation or series of observations therefrom.** Methods suitable for the

operating mode determination procedure 26 include, but are not limited to, a plurality of

mathematical or logic sequence techniques, a plurality of expert system techniques, a

**plurality of fuzzy logic techniques, and a plurality of neural network techniques**

(col. 8, lines 29-39).

**Description of the Surveillance Procedure.** More specifically, and referring to FIG. 3,

**the surveillance procedure 60 is comprised of acquiring successive vectors of**

**current operating data and determining for each such observation vector whether**

**the current operating data is indicative of a fault or failure of the asset 12.** The

surveillance **procedure 60 further includes implementing an alarm or control**

**action for the purpose of notifying an operator or taking a corrective action in**

**response to a detected fault or failure of the asset 12.** The surveillance procedure

60 is in general an open-ended data acquisition and analysis loop that continues until

such time as the operator chooses to terminate the surveillance (col. 8, lines 65-68 and

col. 9, lines 1-9).

The results of the fault detection procedure 68 provide fault detection for

the current vector of observed signal data values. In many cases, fault detection

decision quality is improved by using a fault decision procedure 70 that incorporates

logic for considering a series of observations in making the fault detection decision. The

fault decision procedure 70 may be in general performed using any method suitable for

ascertaining a fault of the asset 12 given a fault detection result or series of fault

detection results therefrom.  Methods suitable for the fault decision procedure 70

include, but are not limited to, single observation techniques (e.g., alarm on every

detected fault), multi-observation voting techniques (e.g., alarm when X out of Y

observations contain a fault indication), **and conditional probability techniques (e.g.,**

**compute the fault probability given a series of fault detection results**).  Upon

completing the fault decision procedure 70, the surveillance procedure then repeats for

as long as -a more data decision procedure 72 determines that additional surveillance

data are available or terminates at surveillance complete step 75 when no more

surveillance data are available (col. 9, lines 63-67 and col. 10, lines 1-16).

In one preferred embodiment of the instant invention; **the method used for**

**parameter estimation is a multivariate state estimation technique (MSET)**

**procedure** (col. 11, lines 7-9). An MSET model is created for the asset 12 using the

MSET training algorithms to learn the inherent data relationships within a set of

historical process operating data.  The **trained MSET model is then used with the**

**MSET parameter estimation and fault detection algorithms to perform the process**

**surveillance function when presented with a new observation of signal data**

**values** (col. 11, lines 37-43). Once the process memory matrix has been constructed,

MSET is used to model the dynamic behavior of the system.  For each current

observation of the system (Xobs), MSET compares the observation vector to the stored

operating states to calculate an estimate of the process parameter values.  The

parameter estimate of the current process state (**Xest) is an n-element vector that is**

**given by the product of the process memory matrix and a weight vector, W (col.**

**12, lines 44-54)**:

$$\vec{X}_{est} = \hat{D} \cdot \vec{W}$$

Truitt is directed to methods for determining alarm conditions. Truitt's system is

computer implemented and capable of executing machine readable instructions.

Bickford is related to fault detection procedures in processes or assets so as to derive a

fault probability based on more than one input signals. The method includes the use of

well known network classifiers and weight vectors and, Bickford explicitly discloses that

such method leads to a high sensitivity surveillance. Thus, it would have been obvious

to one skilled in the art at the time the invention was made to incorporate the algorithms

as taught by Bickford into Truitt's system in order to arrive at the claimed invention. A

person of ordinary skill in the art would have been motivated to do so since this would

lead to the predictable result of alarms with higher sensitivity.

**Claims 6, 19, 20, 25- 27, 32, 33, 42-50, 53** are rejected under 35 U.S.C. 103(a)

as being unpatentable over U. S. Patent 5,910,252 to Truitt in view of U. S. Patent

6,609,036 to Bickford as applied to claims 1 and further in view of U. S. Patent

6,461,329 to Van Antwerp et al. Truitt and Bickford were previously described but does

not teach the detection of fluid outside the circuit or the use of such indication as one of

the signals to generate the alarm. Van Antwerp teaches a liquid detection device for

energizing a warning signal.  An electronic switch, of the non-latching type, is provided

for coupling a source of electrical energy to a warning device responsive to a first signal

at the inputs thereof (Abstract). Truitt and Bickford are directed to fluidic systems with

network classifiers to generate alarm signals in which a plurality of inputs are combined

so as to produce an indication of a leak. In addition, Truitt explicitly discloses the

detection of a cannula or needle dislodgement and Truitt's system operates with

electrical signals. Thus, it would have been obvious to one skilled in the art at the time

the invention was made to incorporate the electronic leak detection device as taught by

Van Antwerp into Truitt's and Bickford's system with the predictable results of obtaining

a more accurate determination of a leakage.

**With regard to claims 27, 32, 33, 43, 53** see rejections under 35 US 112 fourth

paragraph. <u>Parent claim 25 has been interpreted as a method;</u> the above-mentioned

claimed are directed to aspects which appear to denote an "effect of amplifying",

machines used in the medical treatment and data (probability/signals). They have not

been considered as limiting the scope of the claim.


## Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to MARIE ARCHER whose telephone number is (571)270-

3050. The examiner can normally be reached on Monday thru Friday, EST, 7:00 AM to

4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Henry Johnson can be reached on (571)272-4768. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

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/MARIE  ARCHER/                                      /Henry M. Johnson, III/
Examiner, Art Unit 3769                              Supervisory Patent Examiner, Art
                                                     Unit 3769